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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,006	09/14/2000	Patrick K Sullivan	OCEANIT	9060

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,006

Applicant(s)

SULLIVAN ET AL.

Examiner

Patricia C. Mallari

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,16-19,26,28,30-34,37,39,40,45 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,16-19,26,28,30-34,37,39,40,45 and 47-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Drawings

The corrected or substitute drawings were received on 4/11/02. These drawings are accepted.

Claim Objections

Claim 56 objected to because of the following informalities: "third" should be deleted in line 4 of the claim; in line 8 of the claim, "[body from ambient]" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 57 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, comparing the signals from the first sensor with the signals from the third sensor to determine locations of the first and second sensors on the patient is not clearly described in the specification, as claimed in claim 57.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, 16-19, 32, 37, 39, 40, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryars et al. Bryars teaches an apparatus 100 having a sensor assembly 2 comprised of piezo sensors adjacent the radial artery 6. The assembly 2 is connected to a wrist band 3 which also connects to a digital wrist watch 4. The watch 4 contains a microprocessor and display 5. In a preferred embodiment, two piezo sensors 307A and 307B are bonded to a backing plate, and sensor 307B is attached to a bridge assembly such that bridge 312 straddles the radial artery and sensor 307B does not detect the pulse in the artery, only the noise from the local body motion. Signals from sensors 307A and B are amplified and filtered by amplifiers 513 A and B and filters 514 A and B before being supplied to an analog-to-digital (A/D) converter 515 where the combines signals are converted into a digital word and supplied to microprocessor 516 where they are temporarily stored. The amplified and filtered output of background sensor 307A is subtracted by microprocessor 516 from the primary signal produced by sensor 307B to reduce the noise content of the processed signal. A Fast Fourier Transform (FFT) is applied to the signals to detect the pulse (box 1206). The display 517 is connected to the microprocessor 516 and provides the readout of heart rate along with signal amplitude and time of day information (figs. 1-5 & 12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryars et al. in view of Zanetti et al. Bryars teaches an apparatus 100 having a sensor assembly 2 comprised of piezo sensors adjacent the radial artery 6. The assembly 2 is connected to a wristband 3 that also connects to a digital wristwatch 4. The watch 4 contains a microprocessor and display 5. In a preferred embodiment, two piezo sensors 307A and 307B are bonded to a backing plate, and sensor 307B is attached to a bridge assembly such that bridge 312 straddles the radial artery and sensor 307B does not detect the pulse in the artery, only the noise from the local body motion. The amplified and filtered outputs of piezo sensors 307A and 307B are subtracted electronically in the electronic package (processor) 313 to reduce the noise content of the processed signal. Signals from sensors 307A and B are amplified and filtered by amplifiers 513 A and B and filters 514 A and B before being supplied to an analog-to-digital (A/D) converter 515 where the combines signals are converted into a digital word (figs. 1-5, and 12). Bryars lacks a piezoelectric film that is polyvinylidene fluoride. However, Zanetti teaches a piezo-film sensor comprising a polyvinylidene film (col. 7, lines 60-69). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use polyvinylidene film as the piezo-film of Bryars since the two are shown to be functionally equivalent.

Claims 9-11 are rejected under 35U.S.C. 103(a) as being unpatentable over Bryars et al. in view of Zanetti et al., as applied to claims 4, 26, and 28, and further in view of U.s. Patent No. 5,684,460 to Scanlon. Bryars, as modified, lacks a pad incorporating the PVDF film. However, Scanlon teaches a sensor pad 12 incorporating

piezo-electric film with a fluid-filled pad 12 (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Bryars et al. in view of Zanetti et al. with the sensor pad of Scanlon, in order to increase the sensitivity of the sensor.

Claim 30 and 31 is rejected under 35 U.S. C. 103(a) as being unpatentable over Bryars et al. in view of Zanetti et al., as applied to claims 4, 26, 28, and 32, and further in view of Trimmer et al. Bryars, as modified, lacks sensor configured to measure pulse-wave travel time. However, Trimmer teaches a blood pressure and pulse rate measuring apparatus. The apparatus has a sensor head 12 including first and second piezoelectric transducers positioned on the upper arm of a patient via a cuff, as shown in Figure 2, and coupled to electronic computation display module 16 via cable 14. First and second transducers of sensor head 12 measure the rise time at their respective positions and calculate the pulse wave transit time from the rise times (PWTT), wherein the pulse wave velocity is equal to $k/PPWTT$. Module 16 receives the electrical outputs from cable 18 through low pass filters 20 and 22, which are coupled in series with amplifiers 24 and 26. The apparatus analyzes the waveform shape and propagation velocity of the cardiovascular pulse pressure wave as the primary determinants for the blood pressure amplitude and combines this amplitude determination with the results of direct pulse waveform time measurements and mathematical computations to calculate the systolic and diastolic values (figs. 2 & 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood pressure and

rate measuring apparatus of Trimmer et al. with the apparatus of Bryars, in view of Zanetti et al., in order to further provide information with which to diagnose a patient.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryars et al. in view of U.S. Patent No. 5,853,005 to Scanlon. Scanlon teaches an apparatus 100 having a sensor assembly 2 comprised of piezo sensors adjacent the radial artery 6. The assembly 2 is connected to a wristband 3 that also connects to a digital wristwatch 4. The watch 4 contains a microprocessor and display 5. In a preferred embodiment, two piezo sensors 307A and 307B are bonded to a backing plate, and sensor 307B is attached to a bridge assembly such that bridge 312 straddles the radial artery and sensor 307B does not detect the pulse in the artery, only the noise from the local body motion. The amplified and filtered outputs of piezo sensors 307A and 307B are subtracted electronically in the electronic package (processor) 313 to reduce the noise content of the processed signal. Signals from sensors 307A and B are amplified and filtered by amplifiers 513 A and B and filters 514 A and B before being supplied to an analog-to-digital (A/D) converter 515 where the combines signals are converted into a digital word (figs. 1-5, and 7). Bryars lacks incorporating the sensors into a litter.

However, Scanlon discloses an evacuation stretcher (or gurney, for example) 82 with a sensor pad 12 attached. The sensor pad 12 is a fluid filled chamber 11 and a sensing and monitoring system 13 including an acoustic pressure transducer 14, which is preferably piezoelectric. A transmitter, battery, electronic circuitry, and other components of the system can be attached to the straps 81 or the gurney close to the

sensor 13 (fig. 4). Appropriate filtering and noise cancellation techniques can be used to remove or reduce vehicle noise and vibrations, and other transducers or sensors can be combined to enhance signal collection or noise reduction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the stretcher of Scanlon (5,853,005) with the apparatus of Bryars in order to provide pulse rate measurements with little noise in any environment.

Claims 45 and 47-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryars et al. in view of Trimmer et al. Bryars discloses an apparatus 100 having a sensor assembly 2 comprised of piezo sensors adjacent the radial artery 6. The assembly 2 is connected to a wrist band 3 that also connects to a digital wrist watch 4. The watch 4 contains a microprocessor and display 5. In a preferred embodiment, two piezo sensors 307A and 307B are bonded to a backing plate, and sensor 307B is attached to a bridge assembly such that bridge 312 straddles the radial artery and sensor 307B does not detect the pulse in the artery, only the noise from the local body motion. Signals from sensors 307A and B are amplified and filtered by amplifiers 513 A and B and filters 514 A and B before being supplied to an analog-to-digital (A/D) converter 515 where the combines signals are converted into a digital word and supplied to microprocessor 516 where they are temporarily stored. The amplified and filtered output of background sensor 307A is subtracted by microprocessor 516 from the primary signal produced by sensor 307B to reduce the noise content of the processed signal (figs. 1-5, and 7). Bryars lacks measuring the pulse-wave travel time at the plural locations of the sensors on the patient.

However, Trimmer discloses a blood pressure and pulse rate measuring apparatus. The apparatus has a sensor head 12 including first and second piezoelectric transducers positioned on the upper arm of a patient via a cuff, as shown in Figure 2, and coupled to electronic computation display module 16 via cable 14. First and second transducers of sensor head 12 measure the rise time at their respective positions and calculate the pulse wave transit time from the rise times (PWTT), wherein the pulse wave velocity is equal to $k/PPWTT$. Module 16 receives the electrical outputs from cable 18 through low pass filters 20 and 22, which are coupled in series with amplifiers 24 and 26. The apparatus analyzes the waveform shape and propagation velocity of the cardiovascular pulse pressure wave as the primary determinants for the blood pressure amplitude and combines this amplitude determination with the results of direct pulse waveform time measurements and mathematical computations to calculate the systolic and diastolic values (figs. 2 & 7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood pressure and rate measuring apparatus of Trimmer et al. with the apparatus of Bryars et al. in order to further provide information with which to diagnose the patient.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-11, 16-19, 26, 28, 30-34, 37, 39, 40, and 45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm
July 1, 2002

Patricia C. Mallari

Kevin P. Shaver
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